HIPAA PRIVACY RULE
REQUIREMENTS FOR RESEARCH IN
WASHINGTON STATE GOVERNMENT AGENCIES

The final modification to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule was issued on August 14, 2002. The Privacy Rule, found in 45 CFR Part 160 and 45 CFR Part 164, is effective on April 14, 2003. Research activities that involve use and/or disclosure of protected health information (PHI) after that date are subject to certain Privacy Rule requirements. These requirements as they apply to Washington State Government Agencies (the Department of Social and Health Services (DSHS), Department of Health (DOH) and Department of Labor and Industries (L&I)) are explained in this document.

Privacy Rule Definitions

Health Information means any information, whether oral or recorded in any form or medium, that is created or received by a health care provider, health plan or health care clearinghouse, and that relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for provision of health care to an individual.

Individually Identifiable Health Information identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual**.**

Protected Health Information (PHI) means individually identifiable health information transmitted or maintained in any form or medium.

Covered Entity means a health plan, a health care clearinghouse, or a health care provider who transmits any health information in electronic form in connection with a HIPAA-governed transaction. As both a health care plan (Medicaid) and a health care provider, the Department of Social and Health Services (DSHS) is a covered entity. The Department of Health (DOH) has declared itself a hybrid entity. While not required to be a covered entity, the Department of Labor and Industries (L&I) has chosen to become HIPAA-compliant and functions as a covered entity.

Use means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information *within the entity that maintains such information*.

Disclosure means the release, transfer, provision of access to, or divulging in any manner of information *outside the entity holding the information*.

Authorization means written permission allowing a covered entity to use or disclose confidential client information, including protected health information, for research purposes and other purposes not related to treatment, payment, or health care operations.

De-identified Information means health information that does not identify an individual and with respect to which there is no reasonable basis to believe that information can be used to identify an individual. The Privacy Rule in 45 CFR 164.514(b) stipulates very specific requirements that must be met for health information to be considered de-identified.

Limited Data Set means protected health information that excludes specified direct identifiers of the individual or of relatives, employers, or household members of the individual. The Privacy Rule in 45 CFR 164.514(e) specifies the data elements that must be removed for a data set to be considered a limited data set. Under HIPAA, a covered entity may use or disclose a limited data set for research purposes under a data use agreement without review and approval by an IRB. For reasons explained below, however, IRB review is required for use or disclosure of limited data sets created or maintained by DSHS, DOH and L&I.

Minimum Necessary means that, when using or disclosing protected health information, or when requesting protected health information from another covered entity, a covered entity must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. With very limited exceptions (e.g., disclosures to or requests by a health care provider for treatment purposes), the minimum necessary requirements applies to all uses and disclosures of, and requests for, protected health information, including those for research purposes.

PREEMPTION AND COVERAGE ISSUES

The Privacy Rule sets basic standards for the use and disclosure of protected health information for research and non-research purposes. When provisions of the Privacy Rule are contrary to State law, in general, the Privacy Rule preempts the State law. In some instances existing statutes and regulations are *more stringent*, i.e., they provide greater privacy protections to the information and/or greater access by an individual to his or her own information than does the Privacy Rule. In these instances, the more stringent requirement takes precedence.

In some instances researchers may request use and/or disclosure of data sets that include some protected health information and some information which, although individually identifiable, is not considered protected health information. In these instances, the Washington State IRB (WSIRB) will expect researchers to satisfy Privacy Rule requirements for use and/or disclosure of all the information, whether or not it is all considered PHI. When the Privacy Rule does not apply to any of the information in a data set researchers need not meet Privacy Rule requirements for use and/or disclosure of the information. However, researchers must satisfy applicable requirements in other statutes (RCW 70.02; RCW 42.48) and regulations (45 CFR Part 46) for use and/or disclosure of the information even when the Privacy Rule does not apply.

AUTHORIZATION

In general, the Privacy Rule requires a researcher to obtain a valid written authorization from an individual for use and/or disclosure of the individual's protected health information for

research purposes. The Privacy Rule specifies "required elements" that must be in a valid authorization form:

1. A specific description of the information to be used or disclosed;
2. The name of the person or class of persons authorized to make the disclosure;
3. The name of the person or class of persons who will receive the information;
4. A description of each purpose of the use or disclosure;
5. A statement of the ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization;
6. A statement explaining the extent to which the information disclosed is subject to redisclosure by the party that receives the information;
7. A statement that the individual may revoke the authorization in writing, and a description of the exceptions to the right to revoke;
8. An expiration date or expiration event that relates to the individual or the purpose of the use or disclosure;
9. The signature of the individual and the date.

In addition, the authorization must be written in plain language, and a copy of the signed authorization must be provided to the individual.

An authorization for the use and/or disclosure of protected health information for research may be combined with any other type of written permission for the same research study; e.g., the required elements of a valid authorization may be combined with the required elements for informed consent for study participation in one consent document. Alternatively, authorizations for use and/or disclosure of PHI may be prepared on a document separate from the research consent form. Privacy Rule requirements for authorizations are found in 45 CFR 164.508 and in the WSIRB research application.

WAIVER OF AUTHORIZATION

The HIPAA Privacy Rule allows the IRB to approve a waiver of authorization for the use and/or disclosure of protected health information for research purposes when criteria specified in 45 CFR 164.512(i) have been satisfied. The HIPAA criteria for waiver of authorization overlap with criteria in 45 CFR 46.116(d), RCW 70.02.050(g), and RCW 42.48.020 that a researcher also may need to satisfy to obtain individually identifiable personal records without the written authorization of the persons to whom the records pertain. To simplify this task for researchers, the WSIRB research application asks researchers to provide information that address all *applicable* criteria needed by the WSIRB to approve a waiver of authorization for individually identifiable personal records and/or protected health information.

DE-IDENTIFIED INFORMATION

DSHS, DOH and L&I may use or disclose for research purposes data sets and records that have been de-identified per the requirements in the HIPAA Privacy Rule without review and approval by the WSIRB. Specification of the data elements that must be removed from records to meet the de-identification standard are found in 45 CFR 164.514(b).

LIMITED DATA SETS

Although the HIPAA Privacy Rule allows use or disclosure of limited data sets without IRB review and approval, Washington State law on the disclosure of records for research (RCW 42.48) is more stringent, and thus takes precedence over the Privacy Rule on this issue. DSHS, DOH and L&I may use and disclose a limited data set for research purposes only after a research proposal has been reviewed and approved by the WSIRB, and after a legally-binding Confidentiality Agreement between the researcher and the state agency has been established. Standards for constructing a limited data set are found at 45 CFR 164.514(e).

REVIEWS PREPARATORY TO RESEARCH

Under the HIPAA Privacy Rule, a covered entity may allow a researcher to use or access protected health information for "reviews preparatory to research." Permission is conditioned on the researcher "representing" that the use or disclosure is only to review PHI as necessary to prepare a research protocol, that no PHI will be removed from the covered entity, and that the use or access to the PHI is necessary for the research purposes. While the Privacy Rule allows such use or access without IRB review and approval, and without waiver of authorization, Washington State law does not. RCW 42.48.020 requires IRB review and approval of a research proposal and establishment of a legally binding Confidentiality Agreement prior to any use or access to individually identifiable record information held by a state agency for research purposes. This State law makes no provisions for "reviews preparatory to research." As it is more stringent than the Privacy Rule, the State law takes precedence on this issue.

ACCOUNTING FOR DISCLOSURES

The HIPAA Privacy Rule stipulates that an individual has a right to receive an accounting of disclosures of protected information made for research purposes without an authorization. The accounting is for disclosures made in the six years prior to the date on which the accounting is requested. If the disclosures made for a particular research purpose are for 50 or more individuals, the accounting will include the name and a description of the protocol under which the disclosure was made, the date or period of time during which disclosures may have occurred, and the name, address, and telephone number of the research sponsor and the researcher to whom the information was disclosed. WSIRB staff are responsible for responding to requests for an accounting of research disclosures made by DSHS, DOH and L&I.

TRANSITION

Consents, authorizations and waivers of authorizations approved by the WSIRB prior to January 1, 2003, and provided to DSHS, DOH and L&I prior to the April 14, 2003, effective date for the Privacy Rule will be accepted as valid. After January 1, 2003, all authorizations, and all requests for waivers of authorizations, for use and/or disclosure of PHI for research should be in compliance with HIPAA Privacy Rule requirements as they apply to the PHI being used or disclosed. Research that recruits subjects after April 14, 2003, must use a HIPAA-compliant authorization for use and/or disclosure of PHI.